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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N-0143]

High Chemical Co. et al.; Withdrawal of Approval of 13 New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of 13 new drug applications (NDAs) from multiple holders of these applications. The basis for the withdrawals is that the holders of the applications have repeatedly failed to file required annual reports for the applications.

DATES: Effective [insert date of publication in the FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT:

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Center for Drug Evaluation and Research (HFD-7),  
Food and Drug Administration,  
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Rockville, MD 20857,  
301-594-2041.

SUPPLEMENTARY INFORMATION: The holders of approved applications to market new drugs for human use are required to submit annual reports to FDA concerning each of their approved applications in

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accordance with § 314.81 (21 CFR 314.81). In the FEDERAL REGISTER of January 28, 2005 (70 FR 4134), FDA published a notice offering an opportunity for a hearing (NOOH) on a proposal to withdraw approval of 13 NDAs because the firms had failed to submit the required annual reports for these applications. On April 28, 2005, the agency withdrew that notice (70 FR 22054) and reissued the corrected NOOH (70 FR 22052). FDA received two responses to the NOOH:

1. The Kendall Co. (Kendall), 15 Hampshire St., Mansfield, MA 02048, notified the agency that they no longer market the following products: NDA 10-337, Fling Antiperspirant Foot Powder; NDA 10-823, BIKE Foot and Body Powder; and NDA 10-824, BIKE Anti-Fungal Aerosol Spray. Kendall informed FDA that their historical files show they sold their rights to these three products (including the licenses) many years ago; however, they did not notify the agency of the sale. Because Kendall sold the products many years ago, they have no record of the new application holder. Neither The Kendall Co. nor the new license holder requested a hearing.

2. Bayer HealthCare LLC, Biological Products Division, 800 Dwight Way, Berkeley, CA 94701-1966, notified the agency that NDA 10-541, BY-NA-MID (Butylphenamide or B and Zinc Oxide or Stearate) Tincture, Ointment, Lotion, and Powder, is not a product produced at their Berkeley site, and that they would

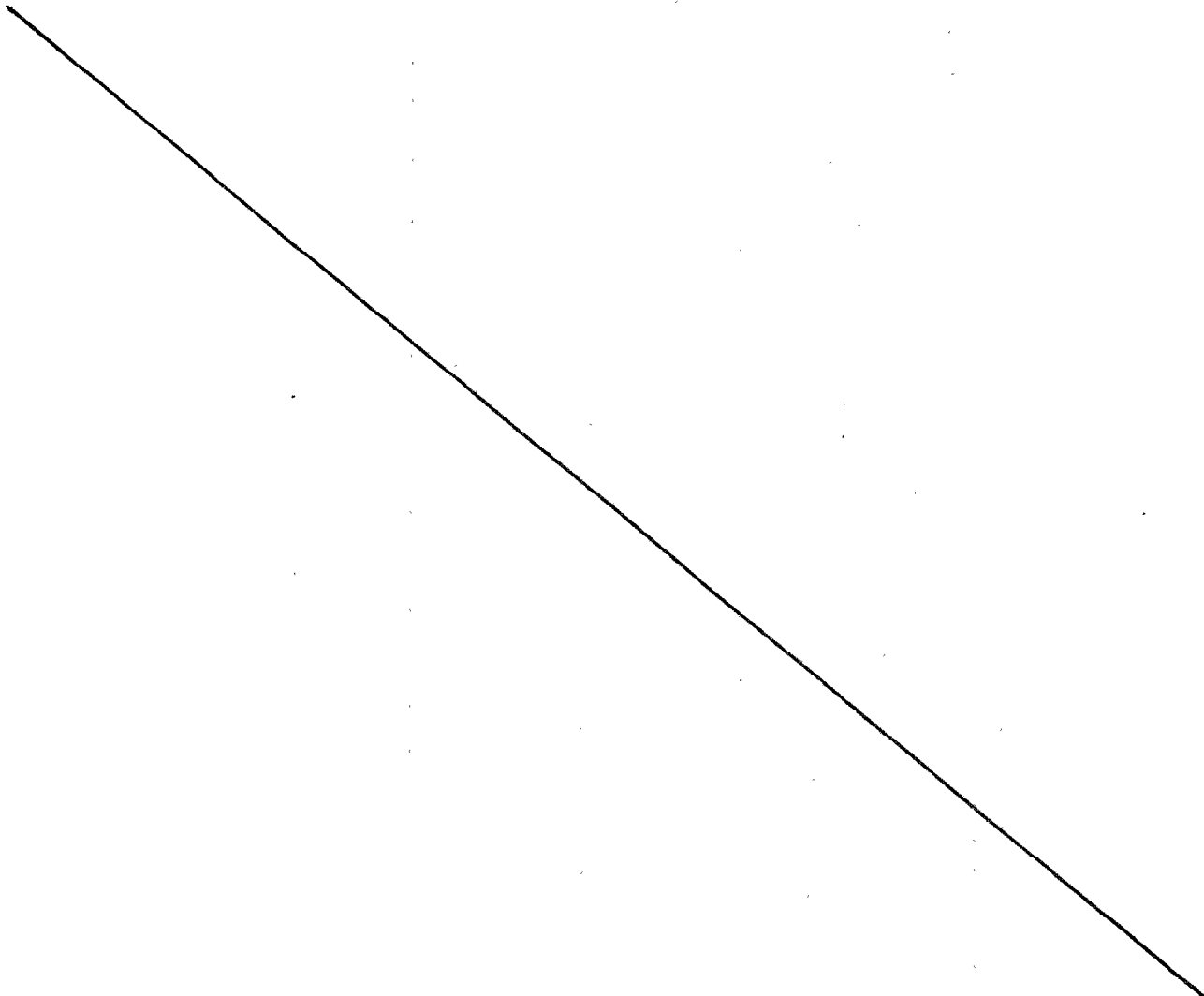
forward the NOOH to Bayer HealthCare LLC, Pharmaceutical Division, 400 Morgan Lane, West Haven, CT 06516-4175. Bayer HealthCare LLC in West Haven, CT, informed the agency that NDA 10-541, BY-NA-MID, is not their product and that they have no regulatory files for this product. Bayer HealthCare LLC did not request a hearing.

No other firms responded to the NOOH. Failure to file a written notice of participation and request for hearing as required by § 314.200 (21 CFR 314.200) constitutes an election by the applicant not to make use of the opportunity for a hearing concerning the proposal to withdraw approval of the applications and a waiver of any contentions concerning the legal status of the drug products. Therefore, the Director, Center for Drug Evaluation and Research, is withdrawing approval of the 13 applications listed in the table of this document.

Application No.	Drug	Applicant
NDA 0-763	Sterile Solution Procaine Injection 2% (Procaine Hydrochloride (HCl))	High Chemical Co., 1760 N. Howard St., Philadelphia, PA 19122
NDA 2-959	Nicotinic Acid (Niacin) Tablets	The Blue Line Chemical Co., 302 South Broadway, St. Louis, MO 63102
NDA 4-236	Sherman (thiamine HCl) Elixir	Do.

Application No.	Drug	Applicant
NDA 4-368	Ascorbic Acid Tablets	Do.
NDA 5-159	D.S.D. (diethylstilbestrol dipropionate)	Do.
NDA 9-452	Multifuge (piperazine citrate) Syrup	Do.
NDA 10-055	Fire Gard Three-Alarm Burn Relief (Methylcellulose)	Gard Products, Inc., 2560 Tara Lane, Brunswick, GA 31520
NDA 10-337	Fling Antiperspirant Foot Powder	Bauer & Black, A Division of The Kendall Co., One Federal St., Boston, MA 02110
NDA 10-541	BY-NA-MID (Butylphenamide or B and Zinc Oxide or Stearate) Tincture, Ointment, Lotion, and Powder	Miles Inc., Cutter Biological, P.O. Box 1986, Berkeley, CA 94701
NDA 10-823	BIKE Foot and Body Powder	Bauer & Black, A Division of The Kendall Co.
NDA 10-824	BIKE Anti-Fungal Aerosol Spray	Do.
NDA 11-233	TKO with Entrin Roll-On Liquid	Modern-Labs, Inc., Maple Rd., Gambrills, MD 21504
NDA 19-432	Spectamine (Iofetamine Hydrochloride I-123) Injection	IMP Inc., 8050 El Rio, Houston, TX 77054

The Director, Center for Drug Evaluation and Research, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)), and under authority delegated by the Commissioner of Food and Drugs, finds that the holders of the applications listed in this document have repeatedly failed to submit reports required by § 314.81. In addition, under § 314.200, we find that the holders of the applications have waived any contentions concerning the legal status of the drug products. Therefore, under these findings, approval of the applications listed in this



document, and all amendments and supplements thereto, is hereby withdrawn, effective [insert date of publication in the FEDERAL REGISTER].

Dated: 8. 29. 05

August 29, 2005.



Steven Galson,  
Director,  
Center for Drug Evaluation and Research.

[FR Doc. 05-????? Filed ??-??-05; 8:45 am]  
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